

WE CLAIM:

1. A space-occupying device for deployment within a patient's stomach comprising:

an expandable member; and

one or more fasteners secured to the expandable member and capable of anchoring the device within the patient's stomach, said one or more fasteners configured such that portions thereof can extend at least partially through the patient's stomach wall but not external to the patient's body.

2. The space-occupying device of claim 1 wherein the expandable member is inflatable.

3. The space-occupying device of claim 1 wherein the fasteners comprise sutures.

4. The space-occupying device of claim 1 wherein the fasteners comprise staples or cable-ties.

5. The space-occupying device of claim 1 wherein the fasteners comprise shape memory or superelastic clips.

6. The space-occupying device of claim 2 further comprising one or more tabs located on and secured to the expandable member.

7. The space-occupying device of claim 6 wherein said one or more tabs, under sufficient force, are capable of at least partially tearing away from and creating a hole in said expandable member.

8. The space-occupying device of claim 2 further comprising a reinforcing patch adhered to said expandable member at the site of attachment of said fasteners.

9. A space-occupying device for deployment within a patient's stomach comprising:

an expandable member; and

means for anchoring the device within the patient's stomach, said anchoring means being capable of extending at least partially through the patient's stomach wall but not external to the patient's body.

10. The space-occupying device of claim 9 wherein the expandable member is inflatable.

11. The space-occupying device of claim 10 further comprising one or more tabs located on and secured to a wall of the expandable member.

12. The space-occupying device of claim 11 wherein said one or more tabs, under sufficient force, are capable of at least partially tearing away from and creating a hole in said expandable member.

13. The space-occupying device of claim 10 further comprising a reinforcing patch adhered to said expandable member at the site of attachment of said fasteners.

14. A space-occupying device for deployment within a patient's stomach comprising:

an inflatable member having one or more sutures attached to said inflatable member, said inflatable member being reinforced at the site of attachment of said sutures.

15. The space-occupying device of claim 14 further comprising one or more tabs located on and secured to a wall of the expandable member.

16. The space-occupying device of claim 15 wherein said one or more tabs, under sufficient force, are capable of at least partially tearing away from and creating a hole in said expandable member.

5 17. A space-occupying device for deployment within a patient's stomach comprising:

an expandable member and an inner deployment member within the expandable member, the inner deployment member being movable from a first position to a second position such that movement of the inner member from the first to second positions expands the expandable member from a first non-
10 expanded state to a second expanded state.

18. The space-occupying device of claim 17 further comprising fasteners secured to the expandable member, the fasteners being capable of anchoring the device within the patient's stomach.
15

19. An assembly for occupying space within a patient's stomach comprising:

an expandable member capable of movement from a first non-
20 expanded state to a second expanded state; and

a deployment member capable of being inserted into the expandable member such that insertion of all or a portion of the deployment member into the expandable member expands the expandable member from a first non-expanded state to a second expanded state.
25

20. The assembly of claim 19 wherein said deployment member comprises an elongate flexible material

21. The assembly of claim 20 wherein said deployment member is of a
30 predetermined shape.

22. The assembly of claim 21 wherein said deployment member is formed of a superelastic or shape memory alloy.

23. The assembly of claim 19 further comprising fasteners secured to the expandable member, the fasteners being capable of anchoring the device within the patient's stomach.

24. A space-occupying apparatus for deployment within a patient's stomach comprising:

an expandable member, said expandable member being capable of being expanded from a first non-expanded state to a second expanded state; and an inner deployment member, said inner deployment member being resilient and having a predetermined shape configured to be retained within the confines of said expandable member when in its second expanded state.

25. The space-occupying apparatus of claim 24 further comprising fasteners secured to the expandable member, the fasteners being capable of anchoring the device within the patient's stomach.

26. A space-occupying apparatus for deployment within a patient's stomach comprising:

an expandable member, said expandable member being capable of being expanded from a first non-expanded state to a second expanded state; and an inner deployment member or members, said inner deployment member or members being capable of expanding said expandable member from said first non-expanded state to said second expanded state upon insertion into the expandable member.

27. The space-occupying apparatus of claim 26 further comprising fasteners secured to the expandable member, the fasteners being capable of anchoring the device within the patient's stomach.

28. A method of anchoring a space occupying device within the stomach of a patient comprising the steps of:

introducing a space occupying device into the patient's stomach wherein said space occupying device includes an
5 expandable member having one or more fasteners attached thereto; and,
fastening said device to the patient's stomach wall such that portions of said fasteners extend at least partially through the patient's stomach wall but do not extend externally of the patient's body.

10 29. The method of claim 28 wherein said fasteners comprise one or more sutures.

15 30. The method of claim 28 wherein said space occupying device is inflatable, and wherein the method further comprises the step of inflating the device after fastening the device to the patient's stomach wall.

31. A method of deploying a space occupying device into the stomach of a patient comprising the steps of:

20 creating an opening into the stomach of the patient;
inserting a guidewire through said opening, such that a first end of said guidewire is located within the patient's stomach and a second end of said guidewire remains external to the patient;
introducing a grasping tool into the patient's mouth, through the patient's throat, and esophagus and into the patient's stomach;
25 grasping said first end of said guidewire with said grasping tool;
removing the grasping tool from the patient's stomach, through the patient's esophagus and throat and out the patient's mouth, thereby locating said first end of said guidewire outside the patient's mouth;
30 providing a space occupying device and securing said one first end of said guidewire to said space occupying device;

applying a force to said second end of said guidewire thereby pulling said device into the patient's mouth, through the patient's throat and esophagus, and into the patient's stomach.

5 32. The method of claim 31 wherein said step of creating a surgical opening further comprises creating a gastric fistula.

33. The method of claim 31 further comprising the step of using an endoscope to visualize or indicate a site for creating said surgical opening.

10

34. The method of claim 31 wherein said step of introducing said grasping tool further comprises the step of inserting an endoscope into the patient's mouth, through the patient's throat and esophagus, and into the patient's stomach and then advancing the grasping tool through the endoscope.

15

35. The method of claim 31 wherein said grasping tool is a snare.

36. The method of claim 31 wherein said space occupying device further comprises one or more sutures secured to said device, and wherein said securing step further comprises securing said one or more sutures to said guidewire.

20

37. The method of claim 36 further comprising the step of suturing said one or more sutures to the patient's stomach wall.

25

38. The method of claim 31 wherein said space occupying device is inflatable and further comprising the step of inflating said device after insertion into the patient's stomach.

30

39. A method of deploying a space occupying device into the stomach of a patient comprising the steps of:

placing a suture into the stomach wall of the patient's stomach such that first and second ends of said suture extend into and are located within the patient's stomach; introducing a grasping tool into the patient's mouth, through the patient's throat, and esophagus and into the patient's stomach;

5 grasping said first and second ends of said suture with said grasping tool;

removing the grasping tool from the patient's stomach, through the patient's esophagus and throat and out the patient's mouth, thereby locating said first and second ends of said suture outside the patient's mouth;

10 providing a space occupying device and securing said one first end of said suture to said space occupying device;

applying a force to said second end of said suture thereby pulling said device into the patient's mouth, through the patient's throat and esophagus, and into the patient's stomach.

15 40. The method of claim 39 wherein said step of introducing said grasping tool further comprises the step of inserting an endoscope into the patient's mouth, through the patient's throat and esophagus, and into the patient's stomach and then advancing the grasping tool through the endoscope.

20 41. The method of claim 39 wherein said step of placing a suture further comprises the steps of

advancing a needle having a needle tip percutaneously at a first angle through the stomach wall of the patient such that the needle tip is located within the patient's stomach;

25 passing the first end of the suture through the needle and into the patient's stomach;

partially withdrawing the needle such that the needle tip is located within the stomach wall;

30 advancing the needle at a second angle until the needle tip is again located within the patient's stomach; and

passing the second end of the suture through the needle and into the patient's stomach.

42. The method of claim 39 further comprising the step of:

5 securing the suture to the device at a location spaced apart from the first secured end after the device has been pulled into the patient's stomach.

43. The method of claim 42 further comprising the step of cutting off
10 excess suture contiguous with the second end of the suture, after the suture has been secured at the spaced apart location on the device.

44. A method of deflating an inflatable space occupying device anchored
within a patient's stomach, said space occupying device having an inflated
expandable member and one or more tabs located on and secured to said
15 expandable member, the method comprising the steps of:

 introducing a grasping tool into the patient's mouth, through the
patient's throat, and esophagus and into the patient's stomach; and

 grasping one of said tabs with said grasping tool and applying a pulling
force sufficient to at least partially tear the tab away from and create a hole in the
20 expandable member, thereby causing the device to deflate.

45. A method of removing an inflatable space occupying device from a
patient's stomach, said space occupying device being anchored within a patient's
stomach and having an inflated expandable member with one or more tabs located
25 on and secured to a expandable member, the method comprising the steps of:

 introducing a grasping tool into the patient's mouth, through the
patient's throat, and esophagus and into the patient's stomach;

 grasping one of said tabs with said grasping tool and applying a pulling
force sufficient to at least partially tear the tab away from and create a hole in the
30 expandable member, thereby causing the device to deflate;

5

sf-1071893